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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/865,950	05/25/2001	Manoussos Perros	PC10925A	6657

7590

10/16/2002

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EXAMINER

HUANG, EVELYN MEI

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 10/16/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/865,950

Applicant(s)

PERROS ET AL.

Examiner

Evelyn Huang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 19-22 and 38-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-9, 38-56 and 59-63 is/are allowed.
- 6) ☒ Claim(s) 19-22, 57, 58 and 64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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1. Claims 1-9, 19-22, 38-64 are pending. Claims 10-18, 23-37 have been canceled according to the preliminary amendment filed on 5-25-2001.

Claim Rejections - 35 USC § 112(2)

2. The amendment has obviated the rejection for claim 22.

The 35 U.S.C. 112 second paragraph rejection is maintained for Claims 19, 20 for reasons of record as set forth in paragraph a, b of the previous office action.

Applicant maintains that claim 19 has been amended to 'CCR5 receptor antagonist compound', thereby obviating the rejection. However, the claim still recites 'a disorder in which the modulation of CCR5 receptor is implicated'. The term 'modulation' includes agonism and antagonism of the receptors, thereby leading to different sets of physiological responses, which are not described in the specification.

Applicant argues that one skilled in the art would understand when a virus is genetically related to HIV, and the exact statement of degree is not required. On the contrary, the term "genetically related" in claim 20 is a relative term which renders the claim indefinite. The degree of homology required to be considered "genetically related" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 112

3. The 35 U.S.C. 112, first paragraph rejection for Claims 19-22 are maintained for reasons of record. The rejection is applicable for new claims 57-58, 64. The specification is enabling only for the use of the inventive compound for treating an inflammatory disease.

Applicant argues that the specification has provided the teaching on the manner and process of making and using the invention commensurate in scope with the claimed subject matter. The burden is on the examiner to come forth with evidence to establish a prima facie case of non-enablement.

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The conclusion that undue experimentation is required to use the invention as claimed is based on the consideration of all the factors (according to *In re Wand*) as a whole as set forth in the previous office action. In view of the state of the art, the high degree of unpredictability of the art, the absence of specific working examples, the scope of the claims does not commensurate with that of the objective enablement, it is concluded that insufficient teaching and guidance have not been provided in the specification to enable one of ordinary skill in the art to practice the invention as claimed without undue experimentation.

Applicant has submitted Reynes in support of the use of a small molecule CCR5 receptor antagonist compound for treating HIV infection. However, the reference is published in 2002, which is two years after the instant priority date of 5/26/2000 and 6/27/2000. At the time of the invention, the use of CCR5 receptor antagonist compound in the treatment of all the diseases as recited in the instant claims have not been described.

Applicant has amended the claims by reciting the instant as antagonist of CCR5 antagonist. However, such a description is not found in the specification. The diseases recited in the instant claims includes any types of renal diseases etc. are known to be of various origins and etiology. The diseases requiring the antagonism and those requiring the activation of the CCR5 receptors have not been described in the specification. Undue experimentation would be required for one of ordinary skill in the art to use the invention as claimed.

Double Patenting

4. The obviousness-type double patenting rejection for Claims 1-9, 19-22, 38-56 over U.S. Application No. 09/454578 is withdrawn upon reconsideration in view of applicant's remarks. The example compounds of the copending application are quite different from the instant. It is not obvious for one of ordinary skill in the art to select the instant from the broad genus of copending compounds.

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Claim Rejections - 35 USC § 112(1)

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The description that the instant compound is a CCR5 receptor antagonist is not found in the specification.

Claim Rejections - 35 USC § 112(2)

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 57, 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For these method claims, the subject to whom the compound is administered is missing but is required.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Allowable Subject Matter

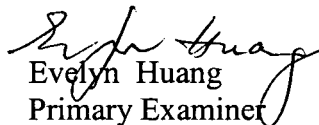
8. Claims 1-9, 38-56, 59-63 are allowed.

The closest prior art is Urch (5968947) wherein the instant is generically disclosed. The triazolyl of the instant, however, is not described by Urch. Motivation to modify Urch's compound to arrive at the instant is lacking.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 703-305-7247. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Evelyn Huang
Primary Examiner
Art Unit 1625

October 8, 2002